S. Little 2/17/04

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#19 Brief w/Ext. 1mo

Applicants	:	Haarala et al.
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For	:	CATHETER SLIT VALVES
Group Art Unit	:	3754
Examiner	:	Buechner, Patrick M.

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APPELLANTS' BRIEF ON APPEAL

This is an appeal from the Office Action dated May 6, 2003 finally rejecting all pending claims in the above-identified application, as further explained by the Advisory Action dated August 20, 2003.

The Final Rejection should be reversed because the derivation of the claimed invention from the cited references following the teachings of the cited references alone would not have been obvious to the person of ordinary skill in the art at the time the invention was made. Rather, the Final Rejection is premised on an impermissible hindsight reconstruction of the prior art in light of Appellants' teachings.

The following sections of this brief are arranged in

the order required by 37 C.F.R. §1.192 and M.P.E.P. §1206:

I. Real Party In Interest

An assignment of the above-identified application from the inventors to SCIMED Life Systems was rded in the Patent Office at frames 252 - 255 of reel 011792 on April 13, 2001. Thus, SCIMED Life Systems is the real party in interest in this appeal.

II. Related Appeals and Interferences

The undersigned representative of the applicants is not aware of any other appeal or interference which will directly affect, or be directly affected by or have a bearing on the Board's decision in this appeal.

III. Status of Claims

The claims pending in the case are claims 43 - 46, all of which were under rejection and on appeal.[1]

Claims 43 - 46 have been rejected under 35 U.S.C. §103 as allegedly obvious over certain prior art.

IV. Status of Amendments

A Response to Final Rejection dated August 6, 2003 has been considered, but was not deemed to place the application in condition for allowance. See, the Advisory Action dated August

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[1] A copy of claims 43 - 46 is attached as Appendix A.

20, 2003. The claims presently pending are as Amended in the Amendment filed March 17, 2003 but apparently received by the Office on March 24, 2003. See, the Office Action dated May 6, 2003.

V. Summary of Invention

The invention relates to a medical device comprising:

- an elongate catheter including an external surface and at least one internal surface defining an internal lumen that extends longitudinally along at least a portion of the elongate catheter; and

- a compound slit extending from a generally hemispherical portion of the external surface to the at least one internal surface and into communication with the internal lumen.

VI. Issues

Whether the medical devices of claims 43, 44 and 46 are unpatentable under 35 U.S.C. § 103 as obvious over over Fig. 9 of Desai (U.S. Patent No. 5,857,464) in view of Leidich (U.S. Patent No. 584,091).

Whether the medical device of claim 45 is unpatentable under 35 U.S.C. § 103 as obvious over Desai in view of Leidich as applied to claim 43 and further in view of Phelps et al. (U.S. Patent No. 6,419,659).

VII. Grouping of Claims

Each of claims 44 and 46 stands with independent claim 43. Dependent claim 45 stands independently of claim 43.

VIII. Argument

The substantive issues on this appeal are:

1. Whether the medical devices of claims 43, 44 and 46 are unpatentable under 35 U.S.C. § 103 as obvious over over Fig. 9 of Desai (U.S. Patent No. 5,857,464) in view of Leidich (U.S. Patent No. 584,091); and

2. Whether the medical device of claim 45 is unpatentable under 35 U.S.C. § 103 as obvious over Desai in view of Leidich as applied to claim 43 and further in view of Phelps et al. (U.S. Patent No. 6,419,659).

It is respectfully submitted that these rejections are in error and must be reversed because the references fail to suggest the claimed elements and they provide no motivation to a person of ordinary skill in the art to combine the teachings of the references in order to produce a medical device as recited in any of claims 43 - 46 of the present application.

It is well established that, for a claim to be unpatentable as obvious:

1. The prior art must suggest the desirability of doing what an applicant has done. Continental Can

Co. v. Monsanto Co., 948 F.2d 1264, 1271, 20 U.S.P.Q. 2d 1746, 1751 (Fed. Cir. 1991).

2. It is improper, therefore, to engage in a hindsight reconstruction of a claimed invention using an applicant's disclosure as a template and selecting elements from the prior art to fill the gaps. In re Gorman, 933 F.2d 982, 987, 18 U.S.P.Q. 2d 1885, 1888 (Fed. Cir. 1991).

3. Put another way, it is improper to modify a prior art reference unless the prior art suggests the desirability of the modification. In re Gordon, 733 F.2d 900, 902, 221 U.S.P.Q. 1125, 1127 (Fed. Cir. 1984). It also is improper to pick and choose from a reference only those parts which support the rejection to the exclusion of other portions which do not. Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc., 796 F.2d 443, 448, 230 U.S.P.Q. 416, 419 (Fed. Cir. 1986). Teachings of a reference which lead away from Appellants' invention are part of the reference and must be considered. In re Mercier, 575 F.2d 1151, 1165, 185 U.S.P.Q. 774, 778 (C.C.P.A. 1975).

4. It is insufficient that the prior art disclosed the components of the patented device, either separately or used in other combinations; there must be some teaching, suggestion or incentive to make the combination made by the inventor. Northern Telecom, Inc. v. Datapoint Corp., 908 F.2d 931, 934 (Fed. Cir. 1991).

5. The nature of the problem which persisted in the art and the inventor's solution are factors to be considered in determining whether the invention would have been obvious to a person of ordinary skill in the art. Northern Telecom, supra., at 908 F.2d 935.

6. A combination invention is not obvious simply because each of its elements is found in different prior art references. It is improper to pick and choose among the individual elements of different references to recreate the claimed invention. SmithKline Diagnostics, Inc. v. Helena Laboratories Corp., 859 F.2d 878, 886-87, 8 U.S.P.Q. 2d 1468, 1475 (Fed. Cir. 1988). The suggestion for making an applicant's combination must come from the prior art, Carella v. Starlight Archery and Pro Line Co., 804 F.2d 135, 140, 231 U.S.P.Q. 644, 647 (Fed. Cir. 1986), and not from applicant's specification. In re Vaeck, 947 F.2d 488, 493, 20 U.S.P.Q. 2d 1438, 1442 (Fed. Cir. 1991). There must be some reason for the combination other than hindsight gleaned from applicant's specification. Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1143, 227 U.S.P.Q. 543, 551 (Fed. Cir. 1985).

7. Not only must the prior art suggest doing what an applicant claims, but the prior art, not applicant's disclosure, must provide both the suggestion and a reasonable expectation of success. In re Vaeck, supra., at 947 F.2d 993, 20

U.S.P.Q. 2d at 1442. Accordingly, neither "obvious to try" nor "obvious to experiment" is the standard for obviousness. Akzo NV v. E.I. dupont denemours, 810 F.2d 1148, 1 U.S.P.Q. 2d 1704, 1707 (Fed. Cir. 1987); In re Dow Chemical Co., 837 F.2d. 469, 473, 5 U.S.P.Q. 2d 1529, 1531 (Fed. Cir. 1988).

8. Art which is non-analogous to Applicants' invention cannot be relied on in support of a rejection under 35 U.S.C. § 103. To determine whether a reference is analogous, the first step is to determine whether the reference is "within the field of inventor's endeavor". In re Deminski, 230 U.S.P.Q. 313 (Fed.Cir. 1986). If it is not, then a determination must be made as to whether the reference is "reasonably pertinent to the particular problem with which the inventor was involved". Id., Strateflex, Inc. v. Aeroquip Corp., 713 F.2d 1530 (Fed. Cir. 1985); also see In re Oetiker, 977 F.2d 1443, 1447 (Fed.Cir. 1992). If this answer is also "no", the reference is deemed non-analogous. A reference is reasonably pertinent if, ... it is one which, because of the matter with which it deals logically, would have commended itself to inventor attention in considering his problem." In re Clay, 966 F.2d 656,659 (Fed. Cir. 1992).

The Final Rejection fails to conform to the foregoing principles. It fails to establish that the references relied upon, taken separately or in combination, suggest to a person of

ordinary skill in the art a medical device as Appellants claim. Rather, the Final Rejection has improperly used Appellants' disclosure as a template, has selected bits and pieces from the references with the benefit of hindsight, and has disregarded evidence supporting patentability. In addition, the rejection improperly relies upon non-analogous art.

1. The References

The Final Rejections of claims 43, 44 and 46 are based upon the following prior art references:

(1) Desai (U.S. Patent No. 5,857,464); and

(2) Leidich (U.S. Patent No. 584,091).

The Final Rejection of claim 45 is based upon prior art references:

(1) Desai (U.S. Patent No. 5,857,464);

(2) Leidich (U.S. Patent No. 584,091); and

(3) Phelps (U.S. Patent No. 6,419,659).

As will be discussed further below, the Examiner has rejected claims 43, 44 and 46 under 35 U.S.C. § 103 as obvious over Desai (specifically, Fig. 9 thereof) in view of Leidich and has rejected claim 45 under 35 U.S.C. § 103 as obvious over Desai in view of Leidich in further view of Phelps et al.

a. Desai

Desai purports to show a catheter for media injection comprising a valve formed at a distal end thereof. No description of the shape of the distal end of the catheter in which the valve is formed is described. The drawings show only a planar surface for this distal end. The valve includes a plurality of flaps which are designed to move apart from one another when acted upon by the force of fluid pressure to permit the guidewire to pass therethrough. This valve is described as reducing the amount of contrast material required for effective angiography while reducing end-hole jets by sealing the distal end.

b. Leidich

Leidich purports to show a valve for a beer tap which includes a plurality of yielding lobes formed by slits extending therethrough. The valve is described as useful in beer taps only and no use with catheters or in any medical application are shown or suggested. The shape of this valve is not described as hemispherical. The valve comes to a point at its distal end and this pointed shape is mirrored on the interior of the valve as well. The shape is described as oval in form - shaped to conform to an inverted arch. There are a wide variety of arch shapes and none of these are specified in the written description of Leidich. However, the valve is shown in the shape of a lancet arch. No other shape is shown or suggested in any figure or in the description. In fact, the siphon tube with which this valve is shown cooperating has a lancet shaped tip.

c. Phelps

Phelps purports to show a plaque treatment catheter including a flexible shaft with a position indicating annular band 46 adjacent its distal end.

2. The Medical Device of Claims 43, 44 and 46 is Not Obvious Over Desai in view of Leidich

It is respectfully submitted that appellants' medical device as recited in claim 43 is not obvious over Desai in view of Leidich as indicated by the Examiner. The Examiner stated, in support of the rejection, that Figure 9 of Desai discloses all limitations of claims 43, 44, and 46 except for the element of a generally hemispherical portion, but that Leidich discloses such an element.

Claim 43 recites a medical device comprising "an elongate catheter including an external surface and at least one internal surface defining an internal lumen that extends longitudinally along at least a portion of the elongate catheter" and "a compound slit extending from a generally hemispherical portion of the external surface to the at least one internal surface and into communication with the internal lumen."

Initially it is noted that the Examiner has relied on Leidich stating that it shows a compound slit extending from a generally hemispherical portion of the external surface of the catheter. However, it is respectfully submitted that the valve A shown in the figures of Leidich is not generally hemispherical. Nor is such a shape described or suggested in the specification. Specifically, the valve A of Leidich is shown as extending along an arc to a point at the distal end thereof. The specification

simply states that the valve A is "preferably oval in form or shaped to conform to an inverted arch." (Specification, col. 1, lines 42 - 43). More specifically, the drawings show the valve A in the shape of an inverted lancet arch. It is respectfully submitted that this shape is clearly not generally hemispherical. Specifically, the point at the distal end of the valve A makes it unsuitable for use in medical procedures as the pointed end may damage tissue as the distal end of a catheter including such a point is inserted into a vessel and moved therethrough. That is, the generally hemispherical shape of the claimed invention presents a smooth distal surface to the tissues with which it comes in contact. It is respectfully submitted that there is no suggestion in Leidich to modify the lancet arch shape to a substantially hemispherical shape. Nor would one of skill in the art have been motivated to make such a modification as the smooth hemispherical shape provides no advantage in tapping beer kegs.

Additionally, applicants submit that Leidich is *non-analogous* to Applicants' invention, and as such, cannot be relied on to reject claims 43 - 46 under 35 U.S.C. § 103(a). The Examiner is directed to a two-step test for determining whether a prior reference is non-analogous and thus not relevant in determining obviousness. The first step is to determine whether the reference is "within the field of inventor's endeavor". In re Deminski, 230 U.S.P.Q. 313 (Fed.Cir. 1986). If it is not, then a determination must be made as to whether the reference is "reasonably pertinent to the particular problem with which the inventor was involved". Id., Strateflex, Inc. v. Aeroquip Corp., 713 F.2d 1530 (Fed. Cir. 1985); also see In re Oetiker, 977 F.2d 1443, 1447 (Fed.Cir. 1992). If this answer is also "no", the reference is deemed non-analogous; therefore it cannot be used for determining obviousness. As indicated above, Applicants

respectfully submit that Leidich constitutes non-analogous art, and thus should not be used as a reference for a Section 103 rejection.

Analyzing the first step of the non-analogous art test, Applicants respectfully submit that Leidich is not within the field of "inventor's endeavor". Applicants' field of endeavor is the field of medical devices generally and, more particularly, is the field of catheters for facilitating medical fluid infusion into and aspiration from a body. In contrast, Leidich's field of endeavor is valves for taps for beer and other liquids. (See Leidich Patent, page 1, lines 12-14). Leidich is in no way concerned with catheters or with medical devices or applications. Therefore, Applicants respectfully submit that Leidich is not within Applicants' field of endeavor; thus the answer to the first part of the non-analogous art two-part test should be "NO".

Turning to the second part of the test, it is now necessary to establish the problem with which Applicants were involved. As stated in Applicants' specification, one of the objects the present invention is to provide a catheter which has a variety of radial and non-radial slits to facilitate aspiration of fluids from and infusion of fluids to a patient's circulatory system. In sharp contrast, Leidich addresses a need for a valve which prevents the accidental escape of air, gas, or fluid from a barrel or cask during the process of tapping. (Specification, col 1 line 14). "A reference is reasonably pertinent if ... it is one which, because of the matter with which it deals logically, would have commended itself to inventor attention in considering his problem." In re Clay, 966 F.2d 656,659 (Fed. Cir. 1992). It is respectfully submitted that problems associated with tapping kegs are not ones which would have commended themselves to

inventors in devising improved catheters.

Furthermore, it is respectfully submitted that the valve A of Leidich is opened only by the forcing of a siphon tube 6 therethrough. In contrast, the device of Desai includes a valve having flaps 42 which are resilient to flex "when acted upon by the force of fluid pressure within." (Specification, col. 5, lines 52 - 53) As described in the background section of Desai, when improperly controlled, liquid leaving the distal end of an angiographic catheter may cause difficulties such as recoil of the catheter and/or premature ventricular contractions and other arrhythmias which endanger the patient and lengthen the procedure. (Specification, col. 1, lines 25 - 44). As mentioned above, the valve A of Leidich is not subjected to fluid pressure from the proximal side and is in no way designed to control a flow of fluid from proximal to distal as in the Desai valve. The valve A of Leidich is designed only: 1) to prevent beer and/or gases from leaking out of a keg before and during tapping; and 2) when opened by the forced introduction of a siphon tube therethrough, to prevent liquids and/or gases from escaping from the keg around the sides of the siphon tube. (Specification, col. 2, lines 53 - 58 and 71 - 83). The only mention of fluid pressure in regard to the Leidich valve is that the fluid pressure within the keg tends to maintain the valve A sealed before it is tapped. (Specification, col. 59 - 64). This valve A is opened only to permit the passage of the siphon tube 6 therethrough and even the flow of beer from the keg is through the siphon tube. Even when opened by the siphon tube 6, the Leidich valve A functions only to prevent flow around the siphon tube 6.

Thus, it is respectfully submitted that Leidich's

particular problem was in no way pertinent to the problem addressed by Applicants, nor would this reference have logically commended itself to Applicants' attention. Only when the referenced disclosure "relates to the same problem as addressed by the claimed invention" is the use of that reference in an obviousness rejection supported. In re GRAP Inc., 35 U.S.P.Q. 2d 1116, 1120 (Fed. Cir. 1995). Therefore, the answer to the second part of the two-part test should also be "NO". With each part answered in the negative, Applicants respectfully submit that Leidich should be considered as non-analogous art, and therefore cannot be used for an obviousness rejection.

In addition, Applicants respectfully submit that, even if Leidich is considered analogous art, neither of the cited references provides any suggestion, incentive or motivation for the combination as suggested by the Examiner. "Multiple cited prior art references must suggest the desirability of being combined and the reference must be viewed without the benefit of hindsight afforded to the disclosure."(emphasis added) In re Paulsen, 30 F.3d 1475, 1482 (Fed. Cir. 1994). "The problem confronted by the inventor must be considered in determining whether it would have been obvious to combine the references in order to solve the problem." Diversitech Corp. v. Century Steps, Inc., 850 F.2d 675, 679 (Fed. Cir. 1998). Applicants respectfully submit that *there is no motivation or incentive to combine* Desai with Leidich to allegedly teach or suggest Applicants' claimed invention.

As stated by the Federal Circuit, "the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on Applicant's disclosure." See In re Vaeck, 947 F.2d

488 (Fed. Cir. 1991).

The Examiner stated that the valve of Leidich functions in the same way as the valve of Desai. "[T]hat is, the valves are both actuated by pressure on the internal surface of the valve...So it would have been obvious to provide the valve of Desai with the structure of the valve as taught by Leidich." (Office Action dated May 6, 2003, page 2). Neither the Examiner nor the cited references say one word as to why one of skill in the art would be motivated to make such a modification. It is respectfully submitted that the only motivation for such a modification is found in the applicants' specification and this modification has been suggested simply to arrive at the structure claimed in this application.

As described above, Leidich describes An Automatic Valve For Beer-Taps for preventing accidental escape of air, gas, or fluid from a barrel or cask during the process of tapping." (Specification, col 1, lines 5 - 14). In contrast, Desai relates to an end hole valve which "functions to curtail undesirable jet effects and to decrease the amount of contrast material and radiation required for optimal angiographic results." (Specification, col 2, line 43). Thus, since Desai and Leidich describe totally different devices (a catheter / a valve for a beer tap), useful in completely separate fields, it is respectfully submitted that neither of these references provides any suggestion, incentive or motivation for the combination and that this combination is an improper hindsight reconstruction.

There are several points in which Leidich and Desai seem to teach away from the proposed combination. Desai asserts that, "[i]nclusion of valve 40 will reduce the quantity of

contrast material required for effective angiography and will eliminate end-hole jets and their concomitant effects." Col 5, line 45. The end-hole jet phenomenon occurs as a result of external fluid injected into an elongate catheter being expelled from a hole in the distal end of the catheter at a high velocity due to the small size of the end hole. Therefore, a purpose of the valve 40 in Desai is to prevent the movement of fluid from the tube 20 *distally* out of the end of the catheter into the bloodstream. As described above, this a problem completely unaddressed by the valve A of Leidich.

The purpose of the valve A of Leidich is to prevent the movement of fluid from the cask *proximally* past the valve A (i.e., from outside the convex surface thereinto). Leidich makes no disclosure concerning the movement of air, gas, or fluid distally and Desai makes no mention of fluid moving proximally.

It is respectfully submitted that neither Desai nor Leidich shows or suggests a medical device comprising an elongate catheter including an external surface and at least one internal surface defining an internal lumen that extends longitudinally along at least a portion of the elongate catheter; and a compound slit extending from a generally hemispherical portion of the external surface to the at least one internal surface as recited in amended claim 43.

Accordingly, Applicants respectfully submit that independent claim 43 is neither shown nor suggested by the above-cited references either taken alone or in combination and that this rejection should be withdrawn. Because claims 44 and 46 depend from and, therefore, include all of the limitations of claim 43, it is respectfully submitted that these claims are

also allowable for the same reasons as indicated above.

In any case, it is respectfully submitted that Leidich is non-analogous art and that the combination of Desai and Leidich is not supported by any motivation provided within either of these references and that this combination of references is improper.

3. The Medical Device of Claim 45 is Not Obvious Over Desai in view of Leidich in further view of Phelps

It is respectfully submitted that appellants' medical device as recited in claim 45, is not obvious over Desai in view of Leidich in further view of Phelps for substantially the same reasons stated above in regard to claims 43, 44 and 46.

The Examiner stated, in support of the rejection, that Desai in view of Leidich as described above shows a device substantially as claimed except for the element of a collar disposed at the distal end of the catheter, but that Phelps discloses a collar 46 disposed adjacent the catheter's distal-most end. The Examiner further stated that it would have been obvious for one of ordinary skill in the art to combine the above mentioned prior art and that "doing so would provide an attending physician with means for determining the location of the catheter by magnetic or electromagnetic means (Phelps column 4, lines 30-35)."

It is respectfully submitted that claim 45 is allowable for the same reasons stated above in regard to claims 43, 44 and 46 as Phelps fails to cure the defects noted above in Leidich and as, in any case, Leidich is not properly combinable with Desai

and Phelps and none of these references provides motivation for the combination suggested by the Examiner.

IX. Conclusion

It is respectfully submitted that appellants have demonstrated that the subject matter of claims 43 - 46 is not obvious in light of the cited art, taken taken alone or in combination. Thus, it is respectfully requested that the Examiner's final rejection of claims 43 - 46 be reversed and all appealed claims found patentable.

The Office is requested to charge the appeal brief fee of $330.00 to our Deposit Account No. 50-1492. The Office is further requested to charge any deficiency or credit over-payment in this case to said Deposit Account.

Respectfully submitted,

Dated: February 5, 2004

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APPENDIX A - APPEALED CLAIMS

43. A medical device comprising:

an elongate catheter including an external surface and at least one internal surface defining an internal lumen that extends longitudinally along at least a portion of the elongate catheter; and

a compound slit extending from a generally hemispherical portion of the external surface to the at least one internal surface and into communication with the internal lumen.

44. A medical device according to claim 43, wherein the compound slit is disposed on a distal end of the elongate catheter.

45. A medical device according to claim 44, further comprising a collar disposed at the distal end of the catheter.

46. A medical device according to claim 43, wherein the compound slit is a tricuspid slit.